**UNITED STATES DISTRICT COURT**
**MIDDLE DISTRICT OF TENNESSEE**
**NASHVILLE DIVISION**

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| **WALTER and BRENDA THOMAS,** | ) | |
| | ) | |
| **Plaintiffs,** | ) | |
| | ) | |
| **v.** | ) | |
| | ) | Case No. _____ |
| **ZIMMER HOLDINGS, INC and ZIMMER, INC.,** | ) | |
| | ) | JURY TRIAL DEMANDED |
| | ) | |
| **Defendants.** | ) | |

## COMPLAINT FOR DAMAGES AND DEMAND FOR JURY TRIAL

Plaintiffs Walter and Brenda Thomas ("Plaintiffs"), by their undersigned counsel, bring this Complaint against Defendants Zimmer Holdings, Inc. and Zimmer, Inc., (hereinafter collectively "Zimmer" and/or "Defendants"), and allege:

## INTRODUCTION

1. This product liability action relates to the design, development, manufacture, testing, marketing, promotion, distribution, and sale of Zimmer's defective hip implant component known as the Durom Acetabular Component ( the "Durom Cup").

2. The Durom Cup was surgically implanted in Plaintiff Walter Thomas on May 14, 2007, and required surgical revision on October 7, 2009, because the Durom Cup was defective and failed. These multiple surgeries caused Plaintiff Walter Thomas to suffer significant injuries, including great pain and agony that restricted his ability to engage in the physical activities he enjoys, and has affected his ability to perform his basic household chores. Plaintiff Brenda Thomas asserts a derivative claim for loss of society, love, comfort and support.

3. Zimmer, founded in 1927, is one of the leading competitors in the U.S. hip and knee replacement market and accounted for seventy percent of the market in 2008.

4. In 2008, the U.S. hip and knee replacement market was valued at $6.7 billion dollars, with the hip replacement market contributing thirty-eight percent of the market at roughly $2.5 billion dollars. According to Zimmer's 2008 Annual 10-K Report, Zimmer was number one in global market share for reconstructive hip components. In the period ending December 2008, Zimmer reported $1,279.5 million in hip component sales. Zimmer's total 2008 sales exceeded $4 billion.

5. Zimmer designs, develops, manufactures, markets, tests, distributes and sells reconstructive orthopedic implants, including joint, dental and spinal implants, trauma products and related orthopedic surgical products. Zimmer's related orthopedic surgical products include surgical supplies and instruments designed to aid in orthopedic surgical procedures.

6. Zimmer's Durom Cup is an orthopedic device used in total hip replacement surgeries. Hip replacement surgery, also known as hip arthroplasty, is a surgical procedure in which the patient's hip joint is resurfaced and replaced with an artificial implant. It is typically used to repair joint/bone damage or to treat arthritis pain in the hip joint area. The hip joint is in essence a large ball-and-socket joint composed of two parts: the head of the thighbone, or femur; and the acetabulum, a cup-shaped bone in the pelvis. Therefore, hip replacement surgery traditionally consists of two tasks: (1) replacing the end of the femur, or thighbone, with an artificial "ball," typically made of metal or stainless steel; and (2) resurfacing the hip socket using a metal shell and plastic liner, into which the ball attached to the femur will fit.

7. During hip replacement surgery, damaged portions of the hip are replaced with smooth, durable artificial surfaces to allow the joint to function properly. The Durom Cup is not cemented or screwed in place during implantation. Instead, it was designed to bond to the patient's hip bone.

8. The outside of the Durom Cup is porous, and has been sprayed with a highly engineered substance (a titanium plasma-sprayed coating) that is intended to facilitate the cup's acceptance by the human body. It is intended that the patient's own bone will grow into the exterior shell of the cup to hold the cup in place.

9. Rather than functioning in the intended manner, the Durom Cup implant resists bone growth and, as a result, instead of adhering to the bone, it comes loose and/or pops free from the hip, which can cause damage to the pelvic bone. This unintended result also causes extreme and devastating pain to the patient and necessitates revision surgery to remove the failed Durom Cup and replace it with a product that functions properly.

10. The Durom Cup is part of a metal-on-metal hip implant system, which was widely marketed by Zimmer as being more durable.

11. According to an article published in the *New York Times* on Thursday March 4, 2010, entitled "Concern Over Metal-on-Metal Implants," "studies in recent years indicate that in some cases the devices can quickly begin to wear, generating high volumes of metallic debris that is absorbed into a patient's body. That situation can touch off inflammatory reactions that cause pain in the groin, death of tissue in the hip joint and loss of surrounding bone." Plaintiff Walter Thomas, like other patients in the studies, likely suffered from metal debris causing death to the soft tissue and bone surrounding his hip, and further decreasing his chances for a successful second hip replacement.

12. The suspension of sales of Zimmer's Durom Cup was announced by Zimmer on July 22, 2008. The defects in the Durom Cup have affected and will continue to affect in the future, thousands of patients who had Durom Cups implanted in their hips. The Durom Cup has been implanted in over 12,000 patients in the United States since it was first sold on the U.S. market in 2006.

13. When introducing the Durom Cup, Zimmer represented to consumers and their physicians that the Durom Cup would provide greater range of motion and less wear on the bearing than traditional hip replacement implant components, thus making it an ideal product for younger, active patients. Contrary to Zimmer's representations, the Durom Cup is prone to an unprecedented failure rate for hip replacement implant components.

14. Since Defendants first began selling the Durom Cup in the United States in 2006 through on or about July 22, 2008, the product labeling and product information for the Durom Cup failed to contain adequate information, instructions, and warnings concerning implantation of the product and the risks that the Durom Cup can loosen and separate from the acetabulum (hip socket) in patients.

15. Despite their knowledge of the defects and serious injuries associated with use of the Durom Cup, Defendants engaged in a marketing and advertising program which, as a whole, by affirmative and material misrepresentations and omissions, falsely and deceptively sought to create the image and impression that the use of the Durom Cup was safe and effective.

16. At all relevant times, Zimmer knew or should have known that the Durom Cup was not safe for the patients in whom it was implanted, including Plaintiff Walter

Thomas, because of the unacceptable failure rate, which is approximately 24%, according to one leading hip surgeon.

17. On information and belief, the failure rate, to date, of Durom Cups implanted in the United States is between 20% and 30%. Since the Durom Cups often fail many months or even sometimes a year or more after the initial surgery, and are continuing to fail in patients, the true failure rate will likely be much higher, as more and more of these devices are failing in patients over time.

18. Notwithstanding the knowledge of predicted failures with the defective Durom Cup, Zimmer continued to sell the Durom Cup for implantation in patients until July 22, 2008, when Zimmer announced a suspension of the sale and distribution of the Durom Cup.

19. Plaintiff Walter Thomas, and other patients in whom the Durom Cups were implanted, have suffered not only physical injuries, but they also bear an unacceptable increase in the risk of severe pain and disability, with or without a costly and painful revision surgery. The revision surgery is invasive and painful and is often needed to replace the defective Durom Cup implant, as it was here.

## PARTIES

20. At all times referenced herein, Plaintiffs Walter and Brenda Thomas were and are citizens of Franklin, Williamson County, Tennessee.

21. Defendant Zimmer Holdings, Inc. is a Delaware corporation with its principal place of business at 345 East Main Street, Warsaw, Indiana, 46580-2746. At all relevant times, Zimmer Holdings, Inc. was the publicly traded holding company with wholly owned subsidiaries, that it controlled, which designed, manufactured, marketed, supplied and sold to distributors, physicians, hospitals, patients and medical practitioners certain hip socket

devices known as the Durom Cup to be surgically implanted in patients throughout the United States, including in the State of Tennessee.

22. Defendant Zimmer, Inc. is a Delaware corporation with its principal place of business at 1800 West Center Street, Warsaw, Indiana, 46581-0708. At all times relevant, Zimmer, Inc was a wholly owned subsidiary of Defendant Zimmer Holdings, Inc. At all times relevant, Defendant, Zimmer, Inc. was duly organized and existing under the laws of the State of Delaware with its principal place of business for manufacturing the Durom Cup in Warsaw, Indiana. Defendant, Zimmer, Inc. designed, manufactured, marketed, supplied and sold the Durom Cup to physicians, hospitals, and clinics to be surgically implanted in patients in the State of Tennessee.

23. Defendant Zimmer, Inc. is a direct subsidiary of the parent company, Defendant Zimmer Holdings, Inc.

24. At all relevant times, each of the Defendants and their directors and officers acted within the scope of their authority of each Defendant and on behalf of each other Defendant. During the relevant times, Defendants possessed a unity of interest between themselves and Zimmer exercised control over its subsidiaries and affiliates. As such, each Defendants are each individually, as well as jointly and severally, liable to Plaintiffs for Plaintiffs' injuries, losses and damages.

## JURISDICTION AND VENUE

25. The Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1332(a) because Plaintiffs and Defendants are citizens of different States and the amount in controversy exceeds $150,000.00 exclusive of interest and costs.

26. Venue in this action properly lies in the Middle District of Tennessee pursuant to 28 U.S.C. §§ 1391 (a) and (c), as a substantial number of the events, actions or

omissions giving rise to Plaintiffs' claims occurred in this District. At all times material hereto, Defendants conducted substantial business in the State of Tennessee and in Davidson County.

27. Upon information and belief, at all relevant times, Defendants were present and transacted, solicited and conducted business in Davidson County, Tennessee, through their employees, agents and/or sales representatives, and derived substantial revenue from such business.

28. At all relevant times, Defendants placed the defective device into the stream of interstate commerce that was implanted in Plaintiff Walter Thomas.

29. Defendants are conclusively presumed to have been doing business in this state and are subject to Tennessee's long arm jurisdiction.

30. At all relevant times, Defendants expected or should have expected that their acts and omissions would have consequences within the United States and the State of Tennessee, including Davidson County.

31. Plaintiffs' damages in this matter accrued in the Middle District of Tennessee.

## FACTUAL ALLEGATIONS

## I. BACKGROUND ON ARTIFICIAL HIPS AND HIP REPLACEMENT DEVICES

32. The human hip joint consists of two parts: a ball and a socket. A portion of the pelvic bone forms a cup-shaped socket; the ball at the top of the thigh bone fits into it. The ball is surrounded with cartilage which, in a healthy hip joint, allows the ball to move smoothly within the socket. Conditions such as osteoarthritis and avascular necrosis can cause degeneration of the hip joint such that hip replacement is required. A hip implant is designed to replicate the human anatomy — that is, the relatively simple ball and socket

structure of the human hip joint. Total hip replacement surgery involves implanting an artificial ball and socket into the patient.

33. The artificial hip implantation process requires a surgeon to insert an artificial cup with a smooth lining into the patient's diseased pelvic socket. The lining serves the same purpose as natural cartilage: allowing for smooth movement of the ball portion of the thigh bone. The diseased or degenerated ball part of the thigh bone is then removed and replaced by a metal or sometimes ceramic ball mounted onto a thin metal stem. The metal stem is then fitted into the thigh bone. Finally, the ball is placed securely into the pelvic socket that has been fitted with the artificial metal cup, where it should move easily, without friction or pain to the patient.

34. Total hip replacement is most commonly used to treat joint failure caused by osteoarthritis. Other indications include rheumatoid arthritis, avascular necrosis, traumatic arthritis, protrusion acetabuli, certain hip fractures, benign and malignant bone tumors, arthritis associated with Paget's disease of the bone, ankylosing spondylitis and juvenile rheumatoid arthritis. The aims of the procedure are pain relief and improvement in hip function. Hip replacement is usually considered only once other therapies, such as pain medications, have failed.

35. Total hip arthroplasty ("THA") , or total hip replacement, is a common medical procedure performed on more than 420,000 patients in the U.S. each year. It is designed to help relieve pain and improve joint function in people with severe hip degeneration due to arthritis or trauma. Traditional devices to replace degenerative hips utilize implantable metal or ceramic heads fitting into a modular metal-backed polyethylene bearing. One concern that historically plagues successful THAs is the wear of the bearing. As

the THA becomes more common among younger patients who want to maintain a physically active lifestyle, alternative bearing surfaces such as cross-linked polyethylene, ceramic-on-ceramic and metal-on-metal have been developed to address the issue of wear. The Durom Cup promised to offer an alternative surface that would resist wear and tear.

36. The Durom Cup is a monoblock (constructed of a single piece of material) cup made of cobalt chromium (CoCr) alloy and is designed for use in combination with Zimmer's Metasul Metal-on-Metal Tribological Solution LDH (Large Diameter Heads) for THA. The design and material of the Durom Cup are key elements to its intended stability, wear resistance, and intended bone sparing characteristics. The Durom Cup has a pure titanium plasma-sprayed coating for fixation. The coating on the Durom Cup sold in the United States has a different structure and is slightly thicker (0.1mm) compared to the same products which were sold for use in patients outside of the United States.

## II. HISTORY OF THE DUROM CUP

37. The Durom Cup was launched in Europe in 2003 for hip resurfacing procedures. Hip resurfacing requires less bone removal than conventional THA, but necessitates a different surgical technique. The Durom Cup was made available in Canada and Australia in 2003, India and Korea in 2005, and Argentina in 2006.

38. On or about December 19, 2005, Zimmer submitted a section 510(k) Premarket Notification of Intent (K053536) to the FDA to manufacture and market the Durom Acetabular Component and the Metasul LDH (Large Diameter Heads) devices to the public. Three months later, on March 19, 2006, the FDA cleared the device for marketing and distribution in the United States.

39. The 510(k) approval process by the FDA is regarded as a simplified "me too" application process, which does not require extensive review and approval by the

FDA. A 510(k) is a premarket submission made to the FDA to demonstrate that the device to be marketed is at least as safe and effective, that is, substantially equivalent, to a legally marketed device that is not subject to premarket approval. Submitters simply must compare their device to one or more legally marketed devices (devices marketed prior to May 28, 1976) and make and support their substantial equivalency claims. The FDA does not perform 510(k) pre-clearance facility inspections and submitters may market the device immediately after 510(k) clearance is granted.

40. In this instance, Zimmer submitted a simplified 510(k) application that compared the Durom Cup to earlier products called "predicate devices" manufactured by competitors. In its application, Zimmer described: "The proposed device has the same intended use, has similar performance characteristics, is manufactured from similar materials using similar processes, and is similar in design to the predicate devices."

41. No clinical studies were conducted in connection with the submission of the application for the Durom Cup. As part of the application process, Defendants stated that the "results of non-clinical analysis demonstrate that the device is safe and effective and substantially equivalent to the predicate device (as implants)." Further in their submission to the FDA the Defendants repeat throughout that the Durom Cup is intended to be a device that is simply similar to previously approved predicate devices. Therefore, the FDA was persuaded by Defendants that any additional review and investigation was unnecessary.

## III. DESIGN & MANUFACTURE OF THE DUROM CUP

42. Zimmer's Durom Cup is a flattened hemisphere, which is meant to offer a greater range and freedom of movement. With a constant wall thickness of 4 mm throughout all sizes, the cup maintains an inner diameter as large as possible, while intended to maintain maximum implant strength and minimum bone resection of acetabular bone mass.

A coating of pure titanium using a plasma spray under vacuum and static load is applied to the outer surface, called Porolock (tm) Ti VPS. The high carbon cobalt chromium (CoCr) alloy is produced by a forging rather than casting process. This means that the size of block carbides is up to eight-times smaller compared to cast cobalt chromium (CoCr) prostheses. The resulting lower surface roughness was intended to lead to a lower wear rate when compared with cast cobalt chromium (CoCr) alloys.

43. Zimmer failed to recognize the deficiencies of the Durom Cup due to poor and inadequate quality assurance procedures, including failure of Zimmer to implement appropriate physical, manual, x-ray, microscopic and other inspections of the Durom Cup. Zimmer failed to implement or utilize adequate safeguards, tests, inspections, monitoring and quality assessments to ensure safety of the defective device. At the time the devices were manufactured and sold to patients, the devices were defectively manufactured and unreasonably dangerous, and did not conform to the federal regulations subjecting patients to risks of injury.

44. During the time Zimmer manufactured the Durom Cup, inadequate manufacturing processes led to material flaws in the quality systems at its manufacturing facilities.

45. During the course of manufacturing the Durom Cup, Zimmer failed in several ways, including, without limitation, by:

(a) failing to conduct adequate mechanical testing on components, subassemblies and/or finished Durom Cup;

(b) failing to test an adequate number of sample devices on an ongoing basis;

(c) failing to take adequate steps to specifically identify failure modes with clarity and suggest methods to monitor, avoid, and/or prevent further failures;

(d) failing to identify and/or note the significance of any testing that resulted in failure of the Durom Cup;

(e) failing to take corrective actions to eliminate or minimize further failures of the Durom Cup;

(f) failing to adequately explain performance specifications for the components, subassemblies, and finished Durom Cup;

(g) failing to adequately explain or justify all test conditions and acceptance criteria for the Durom Cup;

(h) failing to perform adequate testing in an environment that adequately simulated in vivo conditions; and, by

(i) failing to perform adequate quality assurance testing before and after sterilization.

46. Zimmer failed to perform adequate testing of the Durom Cup, including its components and subassemblies, to ensure that the Durom Cup functioned properly during and after implantation.

47. As a result of these manufacturing and quality control problems associated with the manufacture of the Durom Cup, the component was inadequately and defectively manufactured making it adulterated, and outside of the specifications expressly approved by the FDA.

## IV. DUROM CUP DEFECTS ARE EXPOSED BY LEADING PHYSICIANS

48. After the FDA initially approved the 510(k) application, Zimmer began to aggressively market the Durom Cup to physicians and their patients.

49. Relying upon Zimmer's representations, physicians began using broadly the Durom Cup instead of other models. Reports of Durom Cup failures soon followed. It is now apparent that a significant percentage of the Durom Cups have failed, and that the failure rate is unacceptably high.

50. The failure rate is estimated at upwards of 24% (twenty-four percent) when analyzing patients over a four-year period (2006-2010). This failure rate is much higher than similar products made by Zimmer, and is also much higher than the failure rate of competitor's devices. Furthermore, this rate is four times Zimmer's predicted failure rate of 5.7%

51. Lawrence Dorr, M.D., a world-renowned orthopedic surgeon and Zimmer consultant, and a team of doctors at The Arthritis Institute at Good Samaritan Hospital in Los Angeles, California, have recently published the results of their study comparing one hundred and eighty patients who had the large-diameter (44- to 50-mm) Durom Cup and fifty-four patients who had a small-diameter (28-mm Metasul®) articulation implanted between May 2006 and November 2007. The total number of clinical failures was forty-one of one hundred and eighty patients (23%). Twenty-eight of one hundred and fifty-one patients had radiographic impending failure at final follow-up (18.5%). All post-revision surgery retrieved cups were examined in detail and had no evidence of bone on the fixation surface.

52. Since at least 2007, surgeons implanting the Durom Cup complained to Zimmer that the device was failing in their patients, many of whom had to undergo painful, invasive and expensive revision surgeries.

53. One of these surgeons was Dr. Dorr, who warned Zimmer in 2007 of the high rate of Durom Cup failures. At the time Dr. Dorr warned Zimmer of the high rate of failures, he was a paid Zimmer consultant and a veteran of thousands of hip replacement surgeries.

54. In particular, Dr. Dorr informed Zimmer that x-rays showed that the Durom Cup was failing because it was separating or loosening from the bone, rather than fusing to it, causing patients crippling pain while the metal cup moved around the hip socket and rubbed against the bone.

55. Zimmer ignored Dr. Dorr's warnings and continued to sell the Durom Cup.

56. In April 2008, Dr. Dorr publicly warned other orthopedists about the cup failures his patients were experiencing and urged Zimmer to stop selling the Durom Cup.

57. On April 22, 2008, Dr. Dorr wrote the following memorandum to his colleagues at the American Association of Hip and Knee Surgeons:

> *MEMO*
> *DATE: 4/22/08*
> *TO: American Association of Hip and Knee Surgeons*
> *FROM: Larry Dorr, M.D.*
> *RE: This NOTICE is to inform you that we have had ten revisions in 165 hips and have four more that need to be revised using the Durom cup (Zimmer, Inc).*
>
> *This **failure rate** has occurred within the first two years. In the first year the x-rays looked perfect. We have revised four that did not have any radiolucent lines or migration (and John Moreland revised one). These early cups fooled us, but the **symptoms were so***

> ***classic for a loose implant*** *that we operated the patients. When we hit on the edge of the cup* ***it would just pop free****. As time goes by the cups begin developing radiolucent lines. We now have one cup at two years that has actually migrated a short distance. It has tilted into varus.* ***We do not believe the fixation surface is good on these cups****. Also there is a circular cutting surface on the periphery of the cup that we believe* ***prevents the cup from fully seating****.* ***We stopped using the cup after the first revisions****.*
>
> *We have notified Zimmer.* ***The FDA has been notified*** *and we will notify them of our continued revisions. The company does not believe it should pull the cup from the market so I am notifying all of my colleagues of our failure rate with this cup. I went through a similar scenario with the Sulzer cup failures where I was the only one experiencing revisions at the beginning and basically it was assumed that it was our technique.* ***I can assure you that this goes beyond technique****. I learned my lesson in not informing everyone about* ***this magnitude of failures*** *with the Sulzer cup problem, so it is my obligation to do so with this cup.*

(emphasis in original).

58. After informing colleagues about his experience with the Durom Cup, Dr. Dorr heard from several other doctors who reported similar problems. According to Dr. Dorr and other physicians, x-rays of patients who received defective Durom Cups showed that the socket was separating from bone, rather than fusing with it.

59. For patients (including Plaintiff), the slippage of the implant itself, as a result of its failure to adhere to the bone meant agony as the metal cup moved around in the hip socket and rubbed against bone. As a result, Plaintiff Walter Thomas could not walk without assistance. Such crippling injuries are devastating to patients as they were to Mr. Thomas.

60. Despite this memorandum, Zimmer again ignored the warnings and continued to sell the Durom Cup.

61. In late May 2008, Zimmer finally informed surgeons that it was investigating Dr. Dorr's complaint but that it was not suspending sales as Dr. Dorr had

recommended. While Zimmer investigated complaints, roughly 1300 more patients were implanted with the Durom Cup in the United States.

62. Zimmer responded by defending the Durom Cup and blaming the doctors' implantation techniques. Zimmer later attributed failures of the Durom Cup to a discrepancy in doctors' techniques in performing THA surgeries. Zimmer contended (and still apparently contends) that the technology and design parameters of the Durom Cup demand a surgical technique with "high precision and specificity compared to more common and familiar hip arthroplasty surgical techniques practiced in the U.S." Therefore, according to Zimmer, the Durom Cup requires additional training in implantation technique and cup placement for many surgeons who use the device and who may otherwise be experts in THA.

63. Around this time, although Zimmer still maintained that there were no issues with the Durom Cup, other doctors began to stop implanting them. Even still, Zimmer continued to market the Durom Cup to unsuspecting physicians and patients, selling hundreds of units between May 2008 and July 22, 2008.

64. Throughout 2008, while the Durom Cup was being implanted in patients across the United States and around the world, Zimmer was accumulating mounting and overwhelming reports that the Durom Cups were failing at an alarming rate. Zimmer failed to disclose to physicians and patients the true failure rate.

## V. TEMPORARY SUSPENSION OF THE DUROM CUP

65. Zimmer continued to sell the Durom Cup for implantation in patients until July 22, 2008, when Zimmer announced it was temporarily suspending Durom Cup marketing and distribution in the United States. In its announcement, Zimmer stated that the suspension was necessary "while the Company updated labeling to provide more detailed

surgical technique instructions to surgeons and implements its surgical training program in the U.S."

66. Zimmer announced that the company was taking this "voluntary action to address its concerns regarding reports of cup loosening and revisions of the acetabular component used in total hip replacement procedures" but that Zimmer "has found no evidence of a defect in the materials, manufacture, or design of the implant."

## VI. ZIMMER'S IMPROPER FAILURE TO RECALL THE DUROM CUP

67. Under federal regulations, a recall is "a firm's removal or correction of a marketed product that the Food and Drug Administration considers to be in violation of the laws it administers and against which the agency would initiate legal action, e.g., seizure." A recall is an effective method of removing or correcting consumer products that are in violation of laws administered by the FDA.

68. These sections also recognize that recall is an alternative to an FDA-initiated court action for removing or correcting violative, distributed products by setting forth specific recall procedures for the FDA to monitor recalls and assess the adequacy of a firm's efforts in recall. A company's voluntary recall of a medical device and the FDA's classification of that action as a Class I recall establish that the device violates FDA regulations.

69. To date, Zimmer has not issued a public recall of the Durom Cup and instead has described its action as only a "temporary suspension" of the device. In reality, Zimmer has made the device "unavailable for purchase in the United States," (see screen shot from Zimmer e-catalog as published on Zimmer's website on February 23, 2010, attached as **Exhibit A** to this Complaint), but has not voluntarily recalled the device.

## VII. PLAINTIFFS' INJURIES DUE TO THE DEFECTIVE DUROM CUP

70. Plaintiff Walter Thomas, a 63-year-old retired manufacturing plant supervisor from Franklin, Tennessee, and his wife, Brenda Thomas, have been significantly injured as a result of the implantation of the Durom Cup in Plaintiff Walter Thomas's left hip. As a result of the Durom Cup's failure, the Thomas family has had to adjust their lives to accommodate Walter's ongoing injuries.

71. Prior to Plaintiff Walter Thomas's May 14, 2007 implantation surgery, Walter was an energetic husband and father whose active lifestyle included long walks with his dog and working on major remodeling projects in the Thomas's home.

72. The defective Durom Cup limited Plaintiff Walter Thomas's activities because he struggled with bending and turning toward his left side. Walter also struggled in sitting for even short periods of time. As a result, driving became painful and he often squirmed in the vehicle while trying to find a position to minimize the pain. In addition, Walter limped during this time, especially after bending or sitting.

73. Plaintiff Walter Thomas initially did well following his 2007 implantation surgery until it became clear that the Durom Cup was slipping out of place.

74. In August 2009, Plaintiff Walter Thomas visited his orthopedic specialist, who noted that x-rays showed lucency behind the medial acetabular component. Walter's physician was concerned about lack of ingrowth to the acetabular cup and ordered a several confirmatory tests that demonstrated the defect. A revision surgery was thus recommended by his physician at that time.

75. The excruciating pain persisted until Plaintiff Walter Thomas underwent a revision surgery on October 7, 2009, just over two years after the original implantation. The acetabular cup was found to be completely loose, with very little bony in-

growth on the surface. This is exactly the type of Durom Cup failure described by Dr. Dorr that occurred in Dr. Dorr's patients.

76. Plaintiff Walter Thomas never fully recovered from the harm of the defective Durom Cup. Following the revision surgery in October 2009, he suffered complications, necessitating ongoing medical care and several additional hospitalizations.

77. Plaintiff Walter Thomas required a second hip revision, which was performed on February 1, 2010.

78. Mr. Thomas now suffers from a limited range of motion due to the modifications that had to be made to the device and a potentially permanent limp. The dislocations and multiple surgical procedures caused him extreme pain, worry, terrible fear and anxiety, and additional medical expenses.

79. In addition to his medical expenses, Plaintiff Walter Thomas has incurred out-of-pocket expenses for medical aids such as a walker, a cane, two orthotic braces, and items purchased to aid in his ability to function at home, such as a commode riser.

80. In reliance on Zimmer's marketing of the Durom Cup, Plaintiff Walter Thomas and his physician expected that this device would provide him with better stability and range of motion than other hip replacement devices on the market, and that the device would be resistant to wear, making it ideal for very active individuals such as Walter. In addition, Walter and his physician believed that the Durom Cup should last Walter at least twenty years. Walter expected a significant improvement in his quality of life after the initial hip replacement surgery, which did not occur and continues to impact him emotionally and physically.